CALIFORNIA ASSOCIATION of PUBLIC HOSPITALS AND HEALTH SYSTEMS

March 15, 2018

The Honorable Joaquin Arambula
Chair, Subcommittee No. 1 on Health and Human Services, Assembly Committee on Budget
State Capitol, Room 6026
Sacramento, CA 95814

Subject: OPPOSE- Elimination of the use of the 340B Drug Pricing Program in Medi-Cal
REQUEST REJECTION OF TRAILER BILL LANGUAGE

Dear Chairman Arambula:

On behalf of the members of the California Association of Public Hospitals and Health Systems (CAPH), and the millions of patients they serve, I am writing to express our opposition to the Governor's budget proposal to eliminate the use of the 340B Drug Pricing Program in Medi-Cal. The federal 340B Drug Pricing Program (340B Program) requires drug manufacturers to sell costly prescription drugs at discounted prices to safety-net providers, allowing public health care systems to stretch scarce resources to serve more patients and offer more comprehensive services to low-income and vulnerable populations. The current proposal would disproportionately impact large Medi-Cal providers and undermine public health care systems' ability to effectively serve patients in their communities. **CAPH opposes the current budget proposal and requests that the Budget Committee reject it. We also urge the Committee to encourage the Department of Health Care Services (DHCS) to work with 340B providers to establish better mechanisms to ensure compliance within the 340B Program.**

California's 21 public health care systems are the core of the state's health care safety net, delivering high quality care to all who need it, regardless of ability to pay or insurance status. Most patients seen in public health care systems are either Medi-Cal beneficiaries or remain uninsured. Public health care systems provide services to more than 2.85 million Californians annually, provide nearly 30 and 40 percent of the hospital care to the state's Medi-Cal and uninsured populations, respectively, and provide 11.5 million outpatient visits each year. Public health care systems also operate half of the state's top-level trauma and burn centers, and train 57% of all new doctors in the state.

340B Background

Congress established the 340B Program in 1992, with the intent of helping safety-net entities "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Prior to the program's establishment, safety-net providers negotiated discounts directly with drug manufacturers. However, in 1990 a federal program was established that required drug manufacturers to have a national Medicaid rebate agreement with the U.S. Department of Health and Human Services in order to participate in state Medicaid programs. The rebate was based off of manufacturers' lowest price offered to any entity. Consequently, many drug manufacturers stopped providing voluntary safety net discounts. In response, Congress established the 340B Program to protect discounts that safety-net providers had previously been receiving.

[1] H.R. Rep. 102-384, Pt. 2 (1992).

Under the 340B program, as a condition of participation in Medi-Cal, pharmaceutical manufacturers must offer discounted outpatient drugs to 340B participating entities, which include Disproportionate Share Hospitals (DSH), such as public health care systems, district hospitals and other non-profit DSH hospitals; Critical Access Hospitals; Children's Hospitals; Federally Qualified Health Centers; family planning clinics; and Ryan White HIV/AIDS clinics, among other essential safety-net providers. Public health care systems have been eligible for the program since its inception. For-profit hospitals are prohibited from participating in the 340B Program.

The Benefit of 340B to Providers, Patients, and Communities

Pharmaceutical manufacturer discounts provided through the 340B Program allow public health care systems to improve care for all of their patients. The savings that public health care systems receive are reinvested into care delivery improvements, expanded services offered, and maintenance and improvements in high-cost essential community services such as trauma and burn centers. In addition, public health care systems utilize 340B savings to offer specialized, lifesaving programs and services for specific populations that are vital to the communities they serve. Some examples of these additional services include:

- Hepatitis C clinics, such as Arrowhead Regional Medical Center's hepatitis C clinic, which serves as a Hepatology Center of Excellence for the Inland Empire Health Plan, providing lifesaving, curative treatments for Medi-Cal and uninsured patients with hepatitis C;
- Prescription delivery services, such as Alameda Health System's same-day prescription delivery service, which delivers outpatient prescriptions to patients' homes, and helps to overcome transportation barriers and improve medication access for low-income patients;
- Specialized treatments at infusion clinics, such as for congestive heart failure, hemophilia, multiple sclerosis, and cancer;
- HIV clinics: for example, the Owens clinic at UC San Diego Health provides behavioral health services, nutrition services, drug and alcohol counseling, case management support, financial counseling, and patient education. This clinic is also a hub for delivering in-house specialty services to HIV-positive patients (e.g. a liver clinic, a lipid clinic, and an oncology/hematology clinic); and
- Improved access to high cost prescriptions for uninsured patients, who might otherwise forgo these critical medications.

Impact of the Governor's 340B Proposal on Public Health Care Systems

Increased Costs for Safety-Net Providers

The Administration's proposal would dramatically increase pharmaceutical costs for public health care systems. If public health care systems wish to remain in the 340B Program, they would need to purchase Medi-Cal outpatient drugs at wholesale prices, ironically resulting in them paying more for these medications than for-profit hospitals. Most entities that do not participate in the 340B Program (such as for-profit hospitals) participate in other drug discount arrangements, known as group purchasing organizations, which allow entities to band together to obtain bargaining power and negotiate lower drug prices with pharmaceutical manufacturers. The 340B Program prohibits certain hospitals, including public health care systems, from participating in these arrangements. As such, public health care systems would be forced to purchase covered outpatient drugs at list price with no ability to negotiate lower drugs costs, or drop out of the 340B Program altogether. In either scenario, pharmaceutical companies will benefit from the Administration's proposal.

Disproportionate Impact on Safety-Net Providers

As stated, the 340B Program was established to address high prices from drug manufacturers, and to preserve discounts that safety-net providers had been receiving so that they could continue to maximize their reach and effectiveness to low income populations. Contrary to this intent, the Governor's budget proposal would have the biggest impact on providers who serve the largest number of low-income patients, and whose resources are already severely constrained. Public health care systems' Medi-Cal managed care patient mix is 33 percent higher than other hospitals.[2] Over half of all patients at most public health care systems are covered under the Medi-Cal program or are uninsured. As such, public health care systems and other core safety-net providers would be disproportionately impacted by this proposal compared to providers who serve fewer Medi-Cal patients, and who can still obtain significant 340B savings for their commercially insured and Medicare patient populations. The State's proposal undermines the intent of the 340B Program to lower costs for core safety-net providers, and thus public health care systems' ability to effectively serve their communities.

Elimination of Protections against Exorbitant Price Increases

The budget proposal would also eliminate protections in 340B that shield providers from large increases in drug costs. The 340B Program requires pharmaceutical manufacturers to provide extra discounts in cases where the list price of a drug increases at a rate faster than inflation, for both brand-name and generic medications. A significant portion of the discounts currently provided by drug manufacturers under the 340B Program are due to this requirement.[3] Eliminating the use of 340B in Medi-Cal would expose public health care systems to the dramatic price increases that are becoming more and more commonplace in the pharmaceutical industry. For example, the list price of two different forms of insulin, a common drug used to treat diabetes, has increased by 290 percent over the last decade.[4] One 2017 study analyzed nearly 800 commonly used prescription medications and found that average retail prices increased by 6.4 percent in one year alone, compared with the general rate of inflation of .1 percent.[5] Public health care systems and their patients would lose this protection for covered Medi-Cal outpatient drugs under the Administration's proposal.

Putting Safety-Net Services at Risk

If the Administration's proposal is implemented, public health care systems may be forced to reduce or eliminate certain high-cost specialty services and programs, such as hepatitis C clinics, antiretroviral HIV/AIDS programs, or chemotherapy infusion centers, as they would become cost prohibitive to continue to operate. This proposal could significantly hinder access to vital care for some of California's most vulnerable patient populations.

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[2] OSHPD 2015 Annual Financial Disclosure Report where Non-DPH hospitals include all general acute comparable hospitals.

[3] 340B Health. (n.d.). 340B does not increase drug prices. *340B Health* Available at: https://www.340bhealth.org/files/340B_SmallShare_v2.pdf

[4] Ramsey, L. (2016). A 93-year-old drug that can cost more than a mortgage payment tells us everything that's wrong with American health care. *Business Insider.* Available at: http://www.businessinsider.com/insulin-prices-increase-2016-9

[5] Purvis, L, & Schondelmeyerm S. (2017). Rx price watch report: trends in retail prices of prescription drugs widely used by older Americans: 2006 to 2015. *AARP Public Policy Institute.* Available at: https://www.prnewswire.com/news-releases/retail-drug-prices-increase-more-than-50x-faster-than-inflation-rate-300568059.html

Taking Federal Funds out of California

Eliminating 340B in Medi-Cal would reduce overall drug savings in California, as some of the savings from the proposal would go to the federal government. The State is allowed to claim Medicaid rebates for non-340B outpatient drugs; the Administration's proposal would increase the number of drugs for which the state can claim these rebates, shifting the discounts manufacturers provide from safety-net providers to the State. However, not all of these rebate savings would remain in California. Since Medicaid is financed by both the state and federal governments, the federal share of the Medicaid rebate would be returned to Washington. Allowing the 340B program to remain in place for Medi-Cal actually allows more savings to remain in California.

Administration Concerns Regarding Duplicate Discounts

The State has cited concerns about their ability to prevent duplicate pharmaceutical manufacturer discounts, which would occur if the State claimed a rebate on a drug that was already sold to a safety-net provider at the discounted 340B price. Duplicate discounts are prohibited in the 340B Program. While processes have been in place for Medicaid fee-for-service (FFS) to avoid duplicate discounts, similar processes are still under development for Medicaid managed care, as state Medicaid programs have only recently been able to claim these rebates due to changes allowed under the Affordable Care Act. However, there are a number of other approaches available to track 340B claims without compromising the entire program. For example, the state could adopt a similar approach in Medi-Cal managed care that is currently in place in Medi-Cal FFS, to address duplicate discount concerns. We had been in discussions with the State about potential ways to implement such processes when their surprising proposal to eliminate 340B entirely from Medi-Cal was released.

The State's proposal to eliminate 340B entirely goes too far. No other state has entirely eliminated 340B in Medicaid. Public health care systems remain committed to working with the Administration to find a viable solution that would preserve 340B in Medi-Cal, while addressing the State's concern surrounding duplicate discounts.

Trailer Bill Fact Sheet Contains Inaccurate Information

Finally, the Administration released a 340B Budget Trailer Bill Fact Sheet with several statements that we believe to be misleading or inaccurate:

- The State conflates certain federal provisions outlined in the Covered Outpatient Drugs final rule, which requires that reimbursement of drugs purchased under 340B in Medi-Cal FFS be limited to acquisition cost, stating that this requirement also applies to Medi-Cal managed care reimbursement. In fact, the federal Centers for Medicare and Medicaid Services (CMS) has explicitly issued guidance stating that this requirement does *not* apply to Medi-Cal managed care reimbursement.[6]
- The Administration claims that a 2009 state law limits reimbursement of 340B drugs to acquisition cost in Medi-Cal. Yet, the State's own guidance that accompanied this law specifies that this provision is limited to reimbursement under Medi-Cal FFS and County Organized Health System plans.[7]

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[6] Centers for Medicare and Medicaid Services. (2016). Covered Outpatient Drug Final Rule with Comment (CMS-2345-FC) frequently asked questions. *Centers for Medicare and Medicaid Services.* Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/faq070616.pdf

[7] California Department of Health Care Services. (2009). Budget Act of 2009 changes to billing requirements and reimbursement. *State of California.* Available at: https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_10802.asp

- The fact sheet states that safety-net providers participating in the 340B Program are the only entities that have access to a list of 340B drug ceiling prices, and that state Medicaid programs cannot access this information. In reality, participating providers do *not* have access to ceiling prices, and therefore cannot tell when they are being overcharged by drug manufacturers and effectively report manufacturers' non-compliance -- a major criticism of the 340B Program by federal lawmakers.
- CMS has issued guidance directing state Medicaid programs to use the formula provided in section 340B of the Public Health Services Act to calculate ceiling prices.[8]

The above arguments made by the State should be thoroughly investigated before being interpreted as facts, and should be allotted proper time and attention, which cannot be achieved through the budget process.

For all of the reasons listed above, **CAPH requests that the Assembly Budget Committee reject the Governor's 340B proposal.** Should the Legislature wish to move forward with this proposal, we recommend that it be taken up by the appropriate policy committee, where it can be accurately vetted and debated as a policy proposal. We also recommend that DHCS work directly with 340B providers to avoid duplicate discounts. We would be pleased to further discuss our position with you and answer any questions you may have. Please contact Terri Thomas, our Sacramento representative, at 916-325-1010 if you would like to follow-up. Thank you for your consideration.

Sincerely,

Erica Murray
President and CEO

cc: Assemblymember Mathew Harper, Member, Budget Subcommittee No. 1
Assemblymember Devon Mathis, Member, Budget Subcommittee No. 1
Assemblymember Blanca Rubio, Member, Budget Subcommittee No. 1
Assemblymember Jim Wood, Member, Budget Subcommittee No. 1
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[8] Centers for Medicare and Medicaid Services. (2016).